

REMARKS/ARGUMENTS

In response to the Final Office Action mailed August 1, 2008, Applicants propose to amend their application and request reconsideration in view of the proposed amendments and the following remarks. In this amendment, Claim 1 is proposed to be amended, no claims have been added, Claims 2 and 19 were previously cancelled without prejudice and Claims 18 and 20-34 have been previously withdrawn from consideration so that Claims 1, 3-18 and 20-34 are currently pending. No new matter has been introduced.

Claims 1 and 3 were rejected as being unpatentable over U.S. Patent No. 4,214,587 to Sakura, Jr. et al. (Sakura) in view of U.S. Patent No. 6,113,612 to Swanson et al. (Swanson) and Claims 4-17 were rejected as being unpatentable over Sakura and Swanson. These rejections are respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In *re Royka*, 490F.2d 981, 180 USPQ 580 (CCPA 1074). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In *re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In *re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

Sakura discloses an anastomosis device that comprises a cylindrical, radially resilient spring upon which is attached a number of outwardly extending barbs.

Swanson discloses an anastomosis device for joining tubular body fluid conduits. The device comprises a number of sections in a complicated structure. However, Swanson fails to disclose or even suggest the unique combination of Claim 1. Specifically, Swanson fails to disclose the fastening flange and surgical clips as claimed, in Claim 1. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

The present invention, as claimed in amended Claim 1, is directed to a device for joining substantially tubular organisms. The device comprises an anastomosis device, a biocompatible vehicle and at least one therapeutic agent. The anastomosis device includes a fastening flange and a plurality of staples attached thereto and having sharpened ends and barbs. The fastening flange comprises a single wire ring structure having a substantially sinusoidally shaped configuration for a reduced profile delivery and the staples are configured to spring on delivery and to conform to an inverted loop for fastening. The staples extend from the ring structure in the same direction as the sinusoidal wave. The wire ring has an initial shape of a sinusoid, but a substantially flat profile for its final configuration and the staples extend substantially beyond the ring so that they may be everted.

None of the references, whether taken alone or in combination disclose or suggest the unique structure of amended claim 1. Specifically, the references fail to

disclose or suggest a wire ring structure having a sinusoidal shaped configuration for reducing delivery profile. In addition, neither reference discloses staples, that extend beyond the ring for eversion. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

A favorable Action on the merits is earnestly solicited.

Respectfully submitted,

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